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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,745

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Hiroshi Takayama

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,745	Applicant(s) TAKAYAMA ET AL.	
	Examiner MICHAEL SZPERKA	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/17/06, 12/14/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response and amendments received March 3, 2008 are acknowledged.

Claims 6, 7, and 9 have been canceled.

Claims 1-4 and 8 have been amended.

Claims 10 and 11 have been added.

Claims 1-5, 8, 10, and 11 are pending in the instant application.

Applicant's election of Group I, claims 1-5, 8 and new claims 10 and 11 in the reply filed on March 3, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-5, 8, 10, and 11 are under examination in this office action as they read on antibodies that bind human glycoprotein VI (GPVI).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 recites an antibody that binds GPVI and "does not induce a human platelet independently". It is unclear what is meant by this presumably functional limitation. Does the antibody inhibit platelet activation such that molecules including p-selectin are not expressed on the surface of the platelet? Does it mean that new platelets are not formed, i.e. there is no induction of new platelet synthesis via budding off from megakaryocytes? Does it mean something entirely different? Further, given

that platelets are fragments of a megakaryocyte, is the "active fragment" a part of an immunoglobulin or is it something else?

Similar language problems are found in other independent claims. Claim 2 recites an antibody that binds GPVI and "suppresses collagen-mediated human platelet by in vivo administration". What does this phrase mean? It appears additional words are needed to complete the concept that the claim attempts to recite, but in the absence of these words the concept is unknown. Likewise, claim 3 recites the cryptic "decreasing or deleting a collage-mediated of the human platelet by preliminarily contacting with the human platelet" and claim 4 recites "suppresses a collagen-mediated of the human platelet and does not induce a human platelet independently". Further, the phrase "disappearing functional GPVI on the platelet" is awkward and should be amended to better define that which is being claimed. It appears quite clear that the instant claims recite incomplete phrases and ideas and as such it the functional properties of the claimed genus of anti-GPVI cannot be ascertained from the claims in their present form. Appropriate correction is required.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Antibodies are heterodimers comprising a heavy and a light polypeptide chain, with antigen binding specificity being collectively located in the variable heavy (VH) and light domains (VL), more specifically in the CDRs that are located within said variable domains. Applicant has claimed antibodies that minimally comprise either a VH or VL sequence identified by SEQ ID number. The antigen specificity of the resulting antibody is not recited. It is known in the art that an intact VH can be used to screen a VL library

to generate antibodies that bind to a particular antigen of interest, and that this method can be reversed such that a VL can be used to screen a VH library. Such techniques were common and well known to skilled artisans at the time the instant application was filed. However, in order to screen for the other member of the antibody pair, the identity of the target antigen must be known. The instant claim does not recite the target antigen and thus a skilled artisan would be unable to make the recited antibodies because he would not know what the antigen specificity of the ultimate antibody molecule would be and thus would be unable to perform any screening methods. Note that an antibody that does not bind an antigen in general lacks any useful function and thus a skilled artisan would not know how to use such an antibody. Amending the claim to recite that the claimed antibodies bind GPVI would be beneficial in attempting to obviate this rejection. It is noted that claims 5 and 10 recite all 6 CDRs present in an antibody molecule and as such their antigen specificity is inherent, yet for the sake of clarity, completeness and intelligibility of the claimed subject matter it is strongly suggested that claims 5 and 10 also be amended to recite the antigen to which the claimed antibodies bind.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Garman et al. (Nature, 2000, 406:259-266).

Garman et al. disclose the Fc fragment of human IgE in compositions comprising pharmaceutical buffers (see entire document, particularly the abstract and the bottom of the left column of page 265).

It should be noted that all of the rejected claims recite an antibody or an active fragment thereof. The "active fragment" is not recited as being an antigen-binding

fragment that binds GPVI, nor is it recited as necessarily comprising one or more of the peptides recited by SEQ ID numbers. The Fc of human IgE is an "active fragment" because it can bind its ligand (FcεRI) and in so doing give rise to observable biological activity, such as mast cell degranulation.

Therefore, the prior art anticipates the claimed invention.

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Smethurst et al. (WO 03/054020, of record).

Smethurst et al. disclose human antibodies that bind human GPVI as well as pharmaceutical compositions comprising said antibodies (see entire document, particularly the title, abstract, pages 4-5 and 38-40, and claims 1-14). Such antibodies are disclosed for use in treating numerous diseases and disorders characterized by unwanted platelet aggregation, and that said antibodies are disclosed as inhibiting collagen-induced aggregation (see particularly pages 6-8 and claims 6, 7, and 22-35).

Therefore, the prior art anticipates the claimed invention.

8. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Qian et al. (of record as reference B6 on the 12/14/07 IDS).

Qian et al. disclose human antibodies that bind human GPVI and their use in pharmaceutical compositions that comprise said antibodies (see entire document, particularly the abstract and Figures 1-5). Their antibodies are disclosed as inhibiting collagen-induced aggregation (see particularly Figure 5).

Therefore, the prior art anticipates the claimed invention.

9. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Kishimoto et al. (Nucleic Acids Research, 1989, 17:4385).

Kishimoto et al. disclose an antibody comprising a light chain variable domain that is 100% identical to SEQ ID NO:16 of the instant application (see provided sequence alignment).

Therefore, the prior art anticipates the claimed invention.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-4 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13, 20-22, and 24 of copending Application No. 11/816,233. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims anticipate the breadth of the instant claims in that the copending claims recite additional functional limitations and specific amino acid sequences by SEQ ID number for antibodies that bind human GPVI.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-4 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, 22-24, and 26 of copending Application No. 11/912,757. Although the conflicting claims are not

identical, they are not patentably distinct from each other because the copending claims anticipate the breadth of the instant claims in that the copending claims recite additional functional limitations and specific amino acid sequences by SEQ ID number for antibodies that bind human GPVI.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. No claims are allowable.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL SZPERKA whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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